

EXHIBIT 9

BenchMark[®] XT
and
BenchMark LT
Operator Manual

CE

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BenchMark[®] XT
and
BenchMark[®] LT
Operator Manual

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Preface

The BenchMark® XT and The BenchMark LT systems have hardware, software, and reagent components. This manual covers operation, safety information, and maintenance of the BenchMark XT and BenchMark LT systems. Details for each reagent product are covered in their respective package inserts.

First, you are given a quick review of the components of a BenchMark XT and BenchMark LT systems, focused on the hardware. The next section, "Basic Instrument Operation," covers virtually all of the hands-on information you need to operate a BenchMark XT and BenchMark LT instruments on a daily basis.

In "Preventive Maintenance" we cover periodic requirements for cleaning, disinfecting, and system checks. The maintenance chores are very important, and you should read, understand, and follow these directions faithfully.

The BenchMark LT accommodates 20 slides and the BenchMark XT 30 slides. Therefore, in some areas of this manual, figures or text referring to only one of the instruments may be used to illustrate or explain something.

Reference Manuals (English only) that provide additional information are available on the NexES® Software Compact Disk.

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1.0 HOW BENCHMARK XT AND BENCHMARK LT WORKS

The BenchMark XT and BenchMark LT instruments automate the IHC and ISH staining processes. You need only to

- Load slides and reagents
- Keep the computer informed of what you want to do
- Start the process
- Walk away until the slides are ready

The BenchMark XT and BenchMark LT instrument does the rest.

In this section, you will learn the basics that make BenchMark XT and BenchMark LT work. By understanding something about the instrument, you will gain confidence in its capabilities and be better able to diagnose a problem if one should occur.

The BenchMark XT and BenchMark LT instruments are composed of four main components that work together as a system:

- The computer and its software
- The stainer subassembly
- The automated fluidics subassembly (AFS)
 - ◆ The air compressor located in the AFS is controlled by the stainer subassembly
 - ◆ The air compressor located in the AFS supplies pressurized air and bulk liquids to the stainer subassembly through plastic tubing
 - The stainer subassembly will not work without air and bulk fluids
- The waste bottle subassembly
 - ◆ This is two large containers that collect liquid wastes during staining

How BenchMark XT and BenchMark LT Work

The BenchMark XT and BenchMark LT stainer subassemblies are where all of the slide processing operations are performed. They have

- A reagent carousel
- Motors
- Nozzles
- Tubing
- Individual ThermoPads
- Valves
- A dispenser mechanism
- Microcomputers
- Two bar code readers
- Other components

1.1 Carousel and Bar Codes

In essence, the reagent carousel rotates above the slide tray.

- The reagent carousel holds 35 reagent dispensers in five reagent trays
- BenchMark LT holds 20 slides
- BenchMark XT holds 30 slides

The systems keep track of slide and reagent dispenser locations by reading the bar code labels attached to both slides and reagent dispensers.

- The slide bar code specifies the protocol (a customized staining procedure) required for the slide
- The reagent bar code tells the system what reagent or antibody a dispenser contains

The reagent carousel and nozzle plate are rotated in timed steps. As a nozzle, mixer or dispense station passes over a slide, the controller triggers the function appropriate to the slide's protocol.

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1.2 Dual Rinse Station

The first station encountered by a slide is the dual rinse nozzle.

- It is called dual rinse because there are actually two nozzles
 - ◆ The two nozzles are two rows of holes that dispense liquid onto the slide
 - ◆ The nozzles are angled so as to sweep the buffer from the tissue specimen over the edge of the slide
 - ◆ The purpose of the nozzles is to
 - Wash the slide clean of any previously applied reagents or antibodies
 - Leave a carefully controlled amount of buffer solution on the slide



Figure 1. Dual Rinse Nozzles

How BenchMark XT and BenchMark LT Work

1.3 Jet Drain Station

The second station encountered by a slide is the jet drain. The jet drain is a single row of holes that dispense EZ Prep, Reaction Buffer, or SSC to lower the residual slide volume.

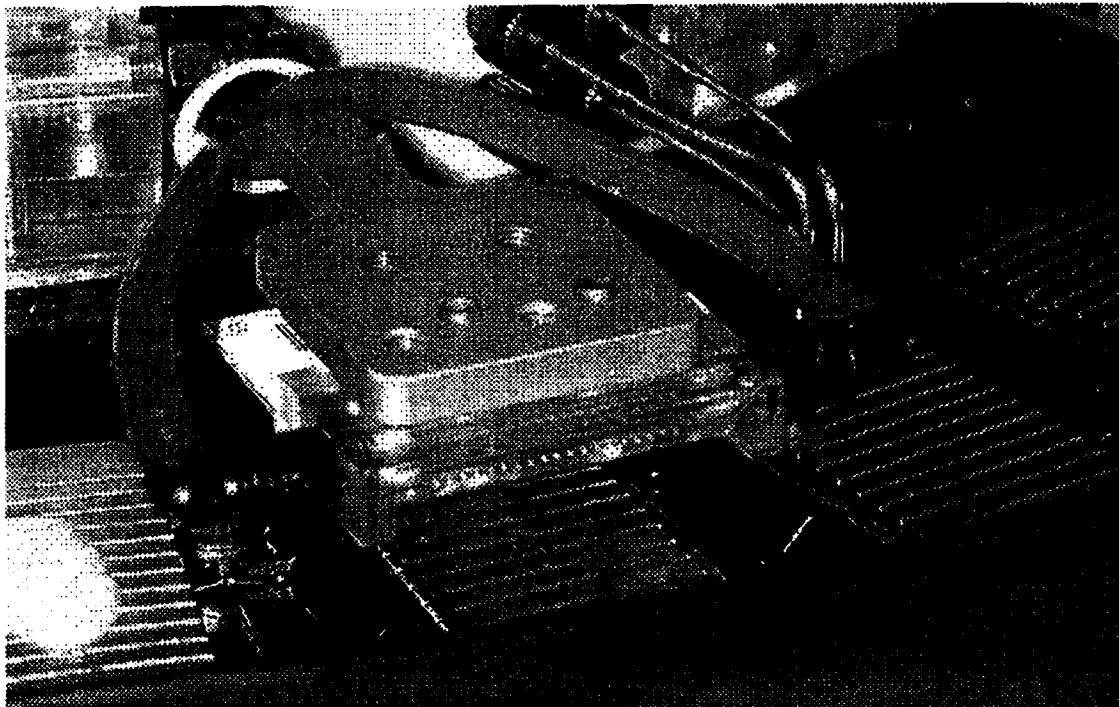


Figure 2. Jet Drain Nozzle

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14.0 APPENDIX

14.1 Intended Use Statement

The BenchMark XT and BenchMark LT systems are intended to automatically stain histological or cytological specimens on microscope slides with specific immunohistochemistry or *in situ* hybridization reagents.

14.2 Parts Supplied by Ventana

Fuses are supplied and installed by Ventana.

14.3 User-Replaceable Fuses

No fuses are user-replaceable.

14.4 Disposal at End of Useful Life

At the end of its useful life, this equipment must be disposed of in accordance with local and/or national environmental requirements.

14.5 List of Accessories

The part number for the list of accessories is 1963500.

14.6 CE Symbols

CE symbols are defined below.